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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,423	10/12/2001	Kirk Hogan	HOGAN-06650	2436

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EXAMINER
GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,423	HOGAN, KIRK	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-71* is/are pending in the application.

4a) Of the above claim(s) *69 and 70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-68 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed May 11, 2003. Currently, claims 45-71 are pending.

Election/Restrictions

2. Applicant's election without traverse of Group II in Paper No. 6 is acknowledged.

3. Newly submitted claims 69 and 70 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

A) Claim 69 is directed to a system comprising a computer readable medium. The claim may be classified in class 702, subclass 20, for example. The system is distinct from the originally elected invention because the system and the kits are patentably distinct products. For example, the system reads upon a computer, whereas the kit claims merely require reagents capable of detecting the presence of variant alleles.

B) Claim 70 is directed to a method for generating the kit of Claim 45. The kit may be made in a materially different method. For example, the kit of Claim 45 may be designed to package the reagents without any selection or assessment of markers.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 69-70 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Priority

4. This application claims priority as a continuation in part of 09/613,887, filed July 11, 2000.

Drawings

5. The drawings are approved by the examiner.

New Matter

6. Claims 46-48, 71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amended claims, reference to "a computer readable medium" and a "decision tree" are included. The amendment fails to point to any support in the specification for the newly added language. However, the specification does not appear to describe or discuss "a computer readable medium" and a "decision tree". The concept of "a computer readable medium" and a "decision tree" does not appear to be part of the originally filed invention. Therefore, "a computer readable medium" and a "decision tree" constitutes new matter. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 45-68, 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 45-68, 71 recite "reagents capable of detecting the presence of variant alleles of two or more genes selected from the group consisting of...." This recitation is indefinite because it is unclear whether the reagents in fact detect the presence of variant alleles of two or more genes. Moreover, it is unclear what constitutes a reagent capable of detecting the presence of variant alleles. It is unclear whether the reagent must be used to differentiate alleles of two or more genes, whether the reagent must be any reagent in any chemical assay used.

Response to Arguments

The response traverses the rejection. The response asserts "it is clear that the claimed reagents provide agents for detecting the variant alleles using the range of different technologies described in the specification." This argument has been thoroughly reviewed, but is not found persuasive because the claim does not require that the reagents in fact detect the presence of variant alleles. The claim could be amended to recite "reagents which detect..." to overcome the rejections.
Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 45, 48-68, 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim 1997 Biochemicals Catalog (page 95, Nucleic Acid Labeling and Detection).

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit.

Boehringer Mannheim provides several products which are packaged for distribution, kits, which allow for detecting the presence of variant alleles of two or more genes. First, Boehringer Mannheim teaches Digoxigenin-3-O-methylcarbony-e-aminocaproic acid-N-hydroxy-succinimide ester which is suitable for 5'-end labeling of oligonucleotides. The label it thus capable of detecting the presence of variant alleles in hybridization assays using ASO probes, for example. Second, Boehringer Mannheim teaches hybridization bags which can be used in non-radioactive hybridization and detection procedures, standard radioactive probe hybridizations and Western blotting

procedures. Third, Boehringer Mannheim teaches lumi-Film Chemiluminescent Detection film which is "ideal for detecting the signals from alkaline phosphatase chemiluminescent substrates in membrane hybridization techniques." These three products are only examples of a few of the products distributed by Boehringer Mannheim which are "capable of detecting the presence of variant alleles of two or more genes."

The claims also require "instructions for using said kit for generating said perioperative genomic profile for said subject." Because no patentable weight is given to the written material in the instructions describing a method, the claim is anticipated by Boehringer Mannheim Catalog. In the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The instructions of the instant kit are not considered to distinguish the claimed kits over the prior art. Moreover, In re Haller states that, in accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. *If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it was intended.* The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Therefore, since Boehringer Mannheim teaches every limitation of the claims, Boehringer Mannheim anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that the prior art does not teach the allele specific elements of the assays of the present claims. This argument has been reviewed but is not convincing because the claims recite "reagents capable of detecting the presence of variant alleles of two or more genes..." This limitation does not require any allele specific elements. Additionally, the claims are drawn to products and not assays, as argued.

The response asserts that "the specification clearly sets forth the appropriate oligonucleotides and components required to detect the polymorphisms of interest." The response continues that none of the references "teaches specific reagents sufficient to detect variant alleles in even one of the genes." This argument has been thoroughly reviewed, but is not found persuasive because, as argued by the response in the 112/2nd rejection above, the specification is clear regarding what constitutes a reagent. The response asserts that some of the examples of reagents include INVADER assay reagents, chips, for example. Thus, the response appears to be encompassing any number of reagents among those reagents permitted to be within the kit.

The response argues that the element of oligonucleotides specific for alleles (i.e. the "ASO probes" that is missing. As stated above, the instant claims require "reagents capable of detecting the presence of variant alleles of two or more genes..." The claims

does not include any recitation with respect to oligonucleotides or more specifically, no recitation of "ASO probes." Rather, the claim broadly encompasses ANY "reagents capable of detecting the presence of variant alleles of two or more genes..." Therefore, the Digoxigenin-3-O-methylcarbony-e-aminocaproic acid-N-hydroxy-succinimide ester which is suitable for 5'-end labeling of oligonucleotides, the hybridization bags which can be used in non-radioactive hybridization and detection procedures, standard radioactive probe hybridizations and Western blotting procedures; and the lumi-Film Chemiluminescent Detection film which is "ideal for detecting the signals from alkaline phosphatase chemiluminescent substrates in membrane hybridization techniques" each meet the limitation of the instant claims.

The response argues that "none of the three references teaches variant alleles of the genes of the present invention. None of the three references teaches detection of variant alleles in two or more genes from the group of genes of the present invention." This argument has been thoroughly reviewed, but is not found persuasive because the claim does not require detection of the variant alleles. The claims are drawn to products comprising a reagent.

With response to the arguments directed to instructions, the response traverses the rejection. The response argues that In re Haller is of no relevance to rejection of the present application. The response argues that "instruction are not a 'statement of intended use', nor are instructions 'mere re-labeling'." However, In re Haller states that, in accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. *If there*

is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it was intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new. The instantly claimed kits contain old products with instructions. The instructions are used to describe how the kit is intended to be used.

Applicant argues that in In re Gulack, the Federal Circuit reversed a Board contention that printed matter could not impart patentability. However, in the case of In re Gulack, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed kit. The components of the kit remain fully functional absent the printed instructions for use. Thus the instructions for use included in a kit or article of manufacture constitute "intended use" for that kit or article of manufacture. Intended used does not impart patentable weight to a product. See MPEP 2111.03:

> Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

In the instant case, the claims are drawn to a kit comprising instructions, and

"reagents capable of detecting the presence of variant alleles of two or more genes..." The intended use which is recited on the instructions lacks a functional relationship to the kit because the instructions do not physically or chemically affect the chemical nature of the components of the kit, and furthermore, the components of the kit can still be used by the skilled artisan for other purposes (as a whole or individually). Therefore, the kit is unpatentable over the prior art because they function equally effectively with or without the instructions, and accordingly no functional relationship exists between the instructions for use and the kit components.

Lastly, in *in re Miller*, (CCPA 1969) 164 USPQ 46, which has as the disclosed invention a set of measuring devices that contain a set of printed indicia upon them referring to fractionated measurements, as well as a legend to such printing, it is stated that "the fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination. Here there is a new and unobvious functional relationship between a measuring receptacle, volumetric indicia thereon indicating volume in a certain ratio to actual volume, and a legend indicating the ratio..." (page 5). This suggests that in order for printed matter to be considered patentable subject matter, there must exist a new and unobvious *functional* relationship between the printed matter and the other elements of the claim. However, in the case of instant claims, no such functional relationship exists. The printed matter merely contains instructions for one use of components of a kit, and no functional relationship exists between the instructions and the other elements of the kit because the components of the kit are capable of functioning without the printed matter.

The response argues that "because novel, unobvious functional relationships clearly exist between the claimed instructions and substrate kits, the present invention surmounts the requirements of the In re Gulack test." Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.
Thus for the reasons above and those already of record, the rejection is maintained.

9. Claims 45, 48-68, 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Perkin Elmer, PCR Systems, Reagents & Consumables (1995-1996, pages 15-18).

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit.

Perkin Elmer provides several products which are packaged for distribution, kits, which allow for detecting the presence of variant alleles of two or more genes. First, Perkin Elmer teaches the GeneAmp PCR Reagent Kit with AmpliTaq DNA polymerase. The kit contains the components of AmpliTaq DNA polymerase, GeneAmp Buffer,

GeneAmp dNTPs, GeneAmp Lambda Control Reagents and package insert with PCR protocols (page 15). This kit provided by Perkin Elmer contains reagents which allow for detection of variant alleles of two or more genes. Perkin Elmer provides several additional variations of the PCR kit (page 16-18).

The claims also require "instructions for using said kit for generating said perioperative genomic profile for said subject." Because no patentable weight is given to the written material in the instructions describing a method, the claim is anticipated by Boehringer Mannheim Catalog. In the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The instructions of the instant kit are not considered to distinguish the claimed kits over the prior art. Moreover, In re Haller states that, in accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. *If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it was intended.* The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Therefore, since Perkin Elmer teaches every limitation of the claims, Perkin Elmer anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that the prior art does not teach the allele specific elements of the assays of the present claims. This argument has been reviewed but is not convincing because the claims recite "reagents capable of detecting the presence of variant alleles of two or more genes..." This limitation does not require any allele specific elements. Additionally, the claims are drawn to products and not assays, as argued.

The response asserts that "the specification clearly sets forth the appropriate oligonucleotides and components required to detect the polymorphisms of interest." The response continues that none of the references "teaches specific reagents sufficient to detect variant alleles in even one of the genes." This argument has been thoroughly reviewed, but is not found persuasive because, as argued by the response in the 112/2nd rejection above, the specification is clear regarding what constitutes a reagent. The response asserts that some of the examples of reagents include INVADER assay reagents, chips, for example. Thus, the response appears to be encompassing any number of reagents among those reagents permitted to be within the kit.

The response argues that the element of oligonucleotides specific for alleles (i.e. the "ASO probes" that is missing. As stated above, the instant claims require "reagents capable of detecting the presence of variant alleles of two or more genes..." The claims does not include any recitation with respect to oligonucleotides or more specifically, no recitation of "ASO probes." Rather, the claim broadly encompasses ANY "reagents capable of detecting the presence of variant alleles of two or more genes..." Therefore,

the kit containing the components of AmpliTaq DNA polymerase, GeneAmp Buffer, GeneAmp dNTPs, GeneAmp Lambda Control Reagents and package insert with PCR protocols meets the limitation of the instant claims.

The response argues that "none of the three references teaches variant alleles of the genes of the present invention. None of the three references teaches detection of variant alleles in two or more genes from the group of genes of the present invention." This argument has been thoroughly reviewed, but is not found persuasive because the claim does not require detection of the variant alleles. The claims are drawn to products comprising a reagent.

With response to the arguments directed to instructions, the response traverses the rejection. The response argues that In re Haller is of no relevance to rejection of the present application. The response argues that "instruction are not a 'statement of intended use', nor are instructions 'mere re-labeling'." However, In re Haller states that, in accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. *If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it was intended.* The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new. The instantly claimed kits contain old products with instructions. The instructions are used to describe how the kit is intended to be used.

Applicant argues that in In re Gulack, the Federal Circuit reversed a Board contention that printed matter could not impart patentability. However, in the case of In re Gulack, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed kit. The components of the kit remain fully functional absent the printed instructions for use. Thus the instructions for use included in a kit or article of manufacture constitute "intended use" for that kit or article of manufacture. Intended used does not impart patentable weight to a product. See MPEP 2111.03:

> Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

In the instant case, the claims are drawn to a kit comprising instructions, and "reagents capable of detecting the presence of variant alleles of two or more genes..." The intended use which is recited on the instructions lacks a functional relationship to the kit because the instructions do not physically or chemically affect the chemical nature of the components of the kit, and furthermore, the components of the kit can still be used by the skilled artisan for other purposes (as a whole or individually). Therefore, the kit is unpatentable over the prior art because they function equally effectively with or without the instructions, and accordingly no functional relationship exists between the instructions for use and the kit components.

Lastly, in *in re Miller*, (CCPA 1969) 164 USPQ 46, which has as the disclosed invention a set of measuring devices that contain a set of printed indicia upon them referring to fractionated measurements, as well as a legend to such printing, it is stated that "the fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination. Here there is a new and unobvious functional relationship between a measuring receptacle, volumetric indicia thereon indicating volume in a certain ratio to actual volume, and a legend indicating the ratio..." (page 5). This suggests that in order for printed matter to be considered patentable subject matter, there must exist a new and unobvious *functional* relationship between the printed matter and the other elements of the claim. However, in the case of instant claims, no such functional relationship exists. The printed matter merely contains instructions for one use of components of a kit, and no functional relationship exists between the instructions and the other elements of the kit because the components of the kit are capable of functioning without the printed matter.

The response argues that "because novel, unobvious functional relationships clearly exist between the claimed instructions and substrate kits, the present invention surmounts the requirements of the In re Gulack test." Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Thus for the reasons above and those already of record, the rejection is maintained.

10. Claims 45, 48-68, 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Applied Biosystems Product Catalog (1993, pages 135-164).

It is noted that these claims contain a preamble which recites an intended use, however, it is also noted that this use does not confer patentable weight on the product claims since the preamble does not materially change what is present in the kit itself and thus represents an intended use of the kit (see MPEP 2111.02). Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit.

Applied Biosystems provides several products which are packaged for distribution, kits, which allow for detecting the presence of variant alleles of two or more genes. Applied Biosystems products for sale include: a DNA analysis system; software for genetic analysis; electrophoresis accessories including combs, alignment braces, glass plates, manuals; PRISM Ready reaction cycle sequencing kits; AmpliTaq Cycling Sequencing Kits; DNA sequencing Neat reagents Dye primers; activated dyes, template purification kits; etc. Each of these products is capable of detecting the presence of variant alleles of two or more genes.

The claims also require "instructions for using said kit for generating said perioperative genomic profile for said subject." Because no patentable weight is given to the written material in the instructions describing a method, the claim is anticipated by Boehringer Mannheim Catalog. In the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA

1947), the court stated "Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The instructions of the instant kit are not considered to distinguish the claimed kits over the prior art. Moreover, In re Haller states that, in accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. *If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it was intended.* The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

Therefore, since Applied Biosystems teaches every limitation of the claims, Applied Biosystems anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts that the prior art does not teach the allele specific elements of the assays of the present claims. This argument has been reviewed but is not convincing because the claims recite "reagents capable of detecting the presence of variant alleles of two or more genes..." This limitation does not require any allele specific elements. Additionally, the claims are drawn to products and not assays, as argued.

The response asserts that "the specification clearly sets forth the appropriate oligonucleotides and components required to detect the polymorphisms of interest."

The response continues that none of the references "teaches specific reagents sufficient to detect variant alleles in even one of the genes." This argument has been thoroughly reviewed, but is not found persuasive because, as argued by the response in the 112/2nd rejection above, the specification is clear regarding what constitutes a reagent. The response asserts that some of the examples of reagents include INVADER assay reagents, chips, for example. Thus, the response appears to be encompassing any number of reagents among those reagents permitted to be within the kit.

The response argues that the element of oligonucleotides specific for alleles (i.e. the "ASO probes" that is missing. As stated above, the instant claims require "reagents capable of detecting the presence of variant alleles of two or more genes..." The claims does not include any recitation with respect to oligonucleotides or more specifically, no recitation of "ASO probes." Rather, the claim broadly encompasses ANY "reagents capable of detecting the presence of variant alleles of two or more genes..." Therefore, the kit containing a DNA analysis system; software for genetic analysis; electrophoresis accessories including combs, alignment braces, glass plates, manuals; PRISM Ready reaction cycle sequencing kits; AmpliTaq Cycling Sequencing Kits; DNA sequencing Neat reagents Dye primers; activated dyes, template purification kits; etc.meets the limitation of the instant claims.

The response argues that "none of the three references teaches variant alleles of the genes of the present invention. None of the three references teaches detection of variant alleles in two or more genes from the group of genes of the present invention."

This argument has been thoroughly reviewed, but is not found persuasive because the claim does not require detection of the variant alleles. The claims are drawn to products comprising a reagent.

With response to the arguments directed to instructions, the response traverses the rejection. The response argues that In re Haller is of no relevance to rejection of the present application. The response argues "instruction are not a 'statement of intended use', nor are instructions 'mere re-labeling'." However, In re Haller states that, in accordance with the patent statutes, an article or composition of matter, in order to be patentable, must not only be useful and involve invention, but must also be new. *If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it was intended.* The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new. The instantly claimed kits contain old products with instructions. The instructions are used to describe how the kit is intended to be used.

Applicant argues that in In re Gulack, the Federal Circuit reversed a Board contention that printed matter could not impart patentability. However, in the case of In re Gulack, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed kit. The components of the kit remain fully functional

absent the printed instructions for use. Thus the instructions for use included in a kit or article of manufacture constitute "intended use" for that kit or article of manufacture. Intended used does not impart patentable weight to a product. See MPEP 2111.03:

> Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

In the instant case, the claims are drawn to a kit comprising instructions, and "reagents capable of detecting the presence of variant alleles of two or more genes..." The intended use which is recited on the instructions lacks a functional relationship to the kit because the instructions do not physically or chemically affect the chemical nature of the components of the kit, and furthermore, the components of the kit can still be used by the skilled artisan for other purposes (as a whole or individually). Therefore, the kit is unpatentable over the prior art because they function equally effectively with or without the instructions, and accordingly no functional relationship exists between the instructions for use and the kit components.

Lastly, in *in re Miller*, (CCPA 1969) 164 USPQ 46, which has as the disclosed invention a set of measuring devices that contain a set of printed indicia upon them referring to fractionated measurements, as well as a legend to such printing, it is stated that "the fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination. Here there is a new and unobvious functional relationship between a measuring receptacle,

volumetric indicia thereon indicating volume in a certain ratio to actual volume, and a legend indicating the ratio..." (page 5). This suggests that in order for printed matter to be considered patentable subject matter, there must exist a new and unobvious *functional* relationship between the printed matter and the other elements of the claim. However, in the case of instant claims, no such functional relationship exists. The printed matter merely contains instructions for one use of components of a kit, and no functional relationship exists between the instructions and the other elements of the kit because the components of the kit are capable of functioning without the printed matter.

The response argues that "because novel, unobvious functional relationships clearly exist between the claimed instructions and substrate kits, the present invention surmounts the requirements of the In re Gulack test." Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Thus for the reasons above and those already of record, the rejection is maintained.

Conclusion

11. No claims allowable over the art.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
June 30, 2003

JEFFREY FREDMAN
PRIMARY EXAMINER